CLAIMS

We claim:

1) A pharmaceutical composition comprising:
   a) oxybutynin;
   b) a second drug for treating incontinence, wherein the second drug is selected from the group consisting of darifenacin and tolterodine; and
   c) at least one pharmaceutical excipient.
2) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is present as a manufactured batch.
3) The pharmaceutical composition of claim 2 comprising:
   a) a homogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.
4) The pharmaceutical composition of claim 2 comprising:
   a) a heterogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.
5) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is present as a unit dose.
6) The pharmaceutical composition of claim 5, wherein at least one of the oxybutynin and the second drug is present in a therapeutically effective amount.
7) The pharmaceutical composition of claim 5, wherein the oxybutynin and the second drug are each present in a therapeutically effective amount.
8) The pharmaceutical composition of claim 5, wherein at least one of the oxybutynin and the second drug is present in a sub-therapeutically effective amount.
9) The pharmaceutical composition of claim 5, wherein the oxybutynin and the second drug are present in sub-therapeutically effective amounts.
10) The pharmaceutical composition of claim 5 comprising:
   a) a homogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.
11) The pharmaceutical composition of claim 5 comprising:
   a) a heterogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.

12) The pharmaceutical composition of claim 1, 2 or 5, wherein the weight ratio of oxybutynin to second drug ranges from 1:0.1 to 1:20.

13) A dosage form comprising:

a) oxybutynin;

b) a second drug for treating incontinence, wherein the second drugs is selected from the group consisting of darifenacin and tolterodine; and

c) at least one pharmaceutical excipient.

14) The dosage form of claim 13 comprising:

a) a first composition comprising oxybutynin and at least one pharmaceutical excipient; and

b) a different second composition comprising the second drug and at least one pharmaceutical excipient.

15) The dosage form of claim 14, wherein the first and second compositions are in admixture.

16) The dosage form of claim 14, wherein the first and second compositions are separate.

17) The dosage form of claim 16, wherein the first and second compositions are in contact with one another.

18) The dosage form of claim 13, wherein at least one of the oxybutynin and the second drug is present in a sub-therapeutically effective amount

19) The dosage form of claim 18, wherein the oxybutynin and second drug together provide a synergistic therapeutic effect when the dosage form is administered to a subject.

20) The dosage form of claim 13, wherein the oxybutynin and second drug are present in therapeutically effective amounts.

21) The dosage form of claim 13, wherein the release profile for oxybutynin and the second drug is independently selected from a controlled, delayed, extended, pulsatile, sustained, immediate, timed, slow, immediate or rapid release when the dosage form is exposed to an aqueous environment.

22) The dosage form of claim 21, wherein oxybutynin and the second drug have approximately the same release profile.

23) The dosage form of claim 21, wherein oxybutynin and the second drug have different release profiles.

24) The dosage form of claim 21, wherein the dosage form provides a controlled release of oxybutynin and the second drug.

25) The dosage form of claim 24, wherein the dosage form provides therapeutically effective plasma levels of oxybutynin and the second drug for a period of at least 12 hours after administration when administered to a subject.

26) The dosage form of claim 13, wherein the dosage form, when administered to a subject, provides an improved toxicity profile as compared to oxybutynin or the second drug when either agent is administered alone to the same subject.

27) The dosage form of claim 13, 18, 20, 21 or 26, wherein the dosage form is selected from the group consisting of a tablet, osmotic device, capsule, tape, suspension, liquid, implant, gel, pill, cream, ointment, inhaler, paste, troche, lozenge, bead, granule, granulation, spheroid, particulate solid, reconstitutable solid, powder, extruded solid, suppository, stick, and mini-pump.

28) A method of treating incontinence in a subject comprising the step of administering a pharmaceutical composition according to any one of claims 1, 5, 6, 8, 10, 11.

29) A method of treating incontinence in a subject comprising the step of administering a dosage form according to any one of claims 13-16, 18, 20-23 or 26.

30) A coated solid dosage form comprising:

a) a core comprising oxybutynin, a second drug for treating incontinence and at least one pharmaceutical excipient, wherein the second drug is selected from the group consisting of darifenacin and tolterodine; and

b) a wall enveloping the core.

31) The dosage form of claim 30, wherein the core comprises:

a) a first composition comprising oxybutynin and at least one pharmaceutical excipient; and

b) a different second composition comprising the second drug and at lease one pharmaceutical excipient.

32) The dosage form of claim 31, wherein the first and second compositions are in admixture.

33) The dosage form of claim 31, wherein the first and second compositions are separate.

34) The dosage form of claim 33, wherein the first and second compositions are in contact with one another.

35) The dosage form of claim 34, wherein the first and second compositions are in stacked arrangement.

36) The dosage form of claim 30 or 31, wherein the release profile for oxybutynin and the second drug is independently selected from a controlled, delayed, extended, pulsatile, sustained, timed, or slow release when the dosage form is exposed to an aqueous environment.

37) The dosage form of claim 36, wherein the dosage form provides a controlled release of oxybutynin and the second drug.

38) The dosage form of claim 36, wherein oxybutynin and the second drug have approximately the same release profile.

39) The dosage form of claim 36, wherein oxybutynin and the second drug have different release profiles.

40) The dosage form of claim 30 or 31, wherein the dosage form is selected from the group consisting of a tablet, bead, osmotic device, granule, suppository, implant, pill, troche, lozenge, and stick.

41) The dosage form of claim 30, wherein the core comprises a homogeneous or heterogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical mixture.

42) The dosage form of claim 41, wherein the wall is microporous, permeable, semipermeable or impermeable.

43) The dosage form of claim 42, wherein the wall further comprises one or more preformed passageways to permit release of oxybutynin and the second drug when the dosage form is exposed to an aqueous environment.

44) The dosage form of claim 41, wherein the wall is a multi-layered wall comprising two or more laminas that are independently selected at each occurrence from inert and drug-containing.

45) The dosage form of claim 44, wherein the two or more laminas are independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

46) The dosage form of claim 44, wherein the two or more laminas are independently selected at each occurrence from water soluble and water erodible.

47) The dosage form of claim 41, wherein the wall is inert or contains drug.

48) The dosage form of claim 47, wherein the wall is water soluble or water erodible.

49) An osmotic device comprising:

a) a core comprising a first composition comprising a first drug and at least one pharmaceutical excipient, and a different second composition comprising a second drug and at least one pharmaceutical excipient, wherein the first and second compositions contact one another and are in stacked arrangement; and

b) a membrane enveloping the core and having at least two passageways to permit a controlled release of the first and second drugs from the core when the osmotic device is exposed to an aqueous environment, wherein at least one first passageway is in communication with the first composition and at least one second passageway is in communication with the second composition.

50) The osmotic device of claim 49, wherein the membrane is semipermeable.

51) The osmotic device of claim 49 further comprising at least one external coat exterior to the membrane.

52) The osmotic device of claim 51, wherein the external coat is independently selected at each occurrence from water soluble and water erodible.

53) The osmotic device of claim 51, wherein the external coat is independently selected at each occurrence from inert and drug-containing.

54) The osmotic device of claim 51, wherein the external coat is independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

55) The osmotic device of claim 49 further comprising at least one internal coat interposed the core and the membrane.

56) The osmotic device of claim 55, wherein the internal coat is independently selected at each occurrence from water soluble and water erodible.

57) The osmotic device of claim 55, wherein the internal coat is independently selected at each occurrence from inert and drug-containing.

58) The osmotic device of claim 55, wherein the internal coat is independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

59) The osmotic device of claim 49, wherein the first drug and the second drug are released sequentially or in an overlapping manner when the osmotic device is exposed to an aqueous environment.

60) The osmotic device of claim 49 further comprising an external coat surrounding the semipermeable membrane, wherein the first passageway has been formed after application of the external coat to the semipermeable membrane and the second passageway has been formed before application of the external coat to the semipermeable membrane such that the second passageway is plugged by the external coat and release of the second drug begins after release of the first drug has started.

61) The osmotic device of claim 49 further comprising an external coat surrounding the semipermeable membrane, wherein the first and second passageways have been formed before application of the external coat to the semipermeable membrane; the first and second passageways are plugged by the external coat; and release of the first drug and the second drug is delayed for a period of time after exposure to an aqueous environment.

62) The osmotic device of claim 50, wherein the first drug and the second drug are released sequentially or in an overlapping manner when the osmotic device is exposed to an aqueous environment.

63) The osmotic device of claim 49, 50, 51, 55, 59 or 62, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

64) An osmotic device comprising:

a) a core comprising a first composition comprising oxybutynin and at least one pharmaceutical excipient, and a different second composition comprising a second drug, selected from the group consisting of darifenacin and tolterodine, and at least one pharmaceutical excipient; and

b) a semipermeable membrane enveloping the core and having at least two passageways to permit controlled release of oxybutynin and the second drug from the core when the osmotic device is exposed to an aqueous environment, wherein at least one passageway is in communication with the first composition and at least one passageway is in communication with the second composition.

65) The osmotic device of claim 64, wherein the first and second compositions contact one another and are in stacked arrangement.

66) The osmotic device of claim 64, wherein, when the osmotic device is exposed to an aqueous environment, oxybutynin is released approximately as follows:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	10
3	5	25
7	20	50
11	40	70
15	58	84
19	70	89
24	76	100

67) The osmotic device of claim 66, wherein the osmotic device provides plasma levels for oxybutynin in the range of about 1-12 ng per ml of plasma.

68) The osmotic device of claim 64, wherein, the second drug is darifenacin and is released approximately as follows when the osmotic device is exposed to an aqueous environment:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	12
3	10	35
7	25	65
11	45	89
15	90	98
24	89	100

69) The osmotic device of claim 64 or 65, the second drug is darifenacin and is released approximately as follows when the osmotic device is exposed to an aqueous environment:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	5
3	0	15
7	10	45
11	29	74
15	52	84

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
19	60	89
24	80	100

70) The osmotic device of claim 64 or 65, wherein the second drug is tolterodine and is released approximately as follows when the osmotic device is exposed to an aqueous environment:

Time (hours)	Minimum Amount Released (%)	Maximum Amount Released (%)
1	0	12
3	3	25
5	17	36
7	31	50
9	49	66
11	61	76
15	74	90
24	76	100

71) The osmotic device of claim 64 or 65, wherein the release of oxybutynin and/or the second drug is delayed.

72) A method of treating incontinence in a subject comprising the step of administering a dosage form according to claim 36.

73) A method of treating incontinence in a subject comprising the step of administering a dosage form according to claim 30-33, 41, 42, 44 or 47.

74) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 64-66 or 68.

75) A dual controlled release osmotic device comprising:

a) a core comprising a first active agent-containing layer and a second active agent-containing layer; and

b) a semipermeable membrane surrounding the core, wherein the membrane comprises at least one preformed passageway in communication with at least one of the first and second active agent-containing layers;

whereby the osmotic device provides a controlled release of the first active agent through the at least one preformed passageway according to a first release profile and the

second layer provides a controlled release of the second active through the at least one preformed passageway according to a second release profile.

76) The osmotic device of claim 75, wherein the layers are in stacked arrangement and in contact with one another.

77) The osmotic device of claim 75, wherein the second active agent-containing layer surrounds the first active agent-containing layer.

78) The osmotic device of claim 76 or 77, wherein the osmotic device comprises at least one first preformed passageway in communication with the first active agent-containing layer and at least one second preformed passageway in communication with the second active agent-containing layer.

79) The osmotic device of claim 76 or 77, wherein the membrane comprises at least one preformed passageway in communication with both the first and second active agent-containing layers.

80) The osmotic device of claim 76 or 77, wherein the membrane comprises at least two preformed passageways and at least one of the two preformed passageways is plugged with a water soluble or water erodible material.

81) The osmotic device of claim 76 or 77, wherein the membrane comprises at least two preformed passageways both of which are plugged with a water soluble or water erodible material, wherein the material plugging the first passageway is the same as the material plugging the second passageway.

82) The osmotic device of claim 76 or 77, wherein the membrane comprises at least two preformed passageways both of which are plugged with a water soluble or water erodible material, wherein the material plugging the first passageway is different than the material plugging the second passageway.

83) The osmotic device of claim 76 or 77 further comprising at least one external coat exterior to the membrane.

84) The osmotic device of claim 83, wherein the external coat is independently selected at each occurrence from water soluble and water erodible.

85) The osmotic device of claim 83, wherein the external coat is independently selected at each occurrence from inert and drug-containing.

86) The osmotic device of claim 83, wherein the external coat is independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

87) The osmotic device of claim 76 or 77 further comprising at least one internal coat interposed the core and the membrane.

88) The osmotic device of claim 87, wherein the internal coat is independently selected at each occurrence from water soluble and water erodible.

89) The osmotic device of claim 87, wherein the internal coat is independently selected at each occurrence from inert and drug-containing.

90) The osmotic device of claim 87, wherein the internal coat is independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

91) The osmotic device of claim 76 or 77, wherein the first drug and the second drug are released sequentially or in an overlapping manner when the osmotic device is exposed to an aqueous environment.

92) The osmotic device of claim 75 further comprising an external coat surrounding the membrane, and the membrane comprises at least a first preformed passageway and at least a second preformed passageway, wherein the first passageway has been formed after application of the external coat to the membrane, and the second passageway has been formed before application of the external coat to the membrane such that the second passageway is plugged by the external coat, and release of the second drug begins after release of the first drug has started.

93) The osmotic device of claim 75 further comprising an external coat surrounding the membrane, and the membrane comprises at least a first preformed passageway and at least a second preformed passageway, wherein the first and second passageways have been formed before application of the external coat to the membrane; and the first and second passageways are plugged by the external coat.

94) The osmotic device of claim 93, wherein release of the first drug and the second drug is delayed for a period of time after exposure to an aqueous environment.

95) The osmotic device of claims any one of claims 75, 76 or 77, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

96) The osmotic device of claim 78, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

97) The osmotic device of claim 79, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

98) The osmotic device of claim 80, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

99) The osmotic device of claim 81, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

100) The osmotic device of claim 82, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

101) The osmotic device of claim 83, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

102) The osmotic device of claim 87, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

103) The osmotic device of claim 91, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

104) The osmotic device of claim 92 or 93, wherein each drug is independently released according to a timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, second order and/or delayed release profile.

105) The dosage form of claim 16, wherein the first and second compositions are not in contact with one another.

106) The dosage form of claim 14, wherein at least one of the oxybutynin and the second drug is present in a sub-therapeutically effective amount

107) The dosage form of claim 14, wherein the oxybutynin and second drug are present in therapeutically effective amounts.

108) The dosage form of claim 13 comprising:

a) a homogeneous or homogeneous mixture of oxybutynin, the second drug and at least one pharmaceutical excipient.

109) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 69.

110) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 70.

111) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 71.

112) An osmotic device comprising:

a) a core comprising a first composition comprising oxybutynin and at least one pharmaceutical excipient, and a different second composition comprising a second drug, selected from the group consisting of darifenacin and tolterodine, and at least one pharmaceutical excipient, wherein the first and second compositions contact one another and are in stacked arrangement; and

b) a semipermeable membrane enveloping the core and having at least two passageways to permit controlled release of oxybutynin and the second drug from the core when the osmotic device is exposed to an aqueous environment, wherein at least one passageway is in communication with the first composition and at least one passageway is in communication with the second composition;

wherein, when the osmotic device is exposed to an aqueous environment, oxybutynin is released approximately as follows:

Time (hs)	Amount Released (%)	
	Min	Max
1	0	10
3	5	25
5	17	36
7	20	50
11	40	70
15	58	85
19	70	90
24	76	100

113) The osmotic device of claim 112, wherein, when the osmotic device is exposed to an aqueous environment, the second drug is released approximately as follows:

Time (hs)	Amount Range (%)	
	Min	Max
1	0	12
3	3	25
5	17	36
7	31	50
9	49	66
11	61	76
15	74	90
24	76	100

114) The osmotic device of claim 112 or 113, wherein the second drug is darifenacin, and the osmotic device provides a single dose plasma level for darifenacin that is sufficient to provide the desired therapeutic response.

115) The osmotic device of claim 112 or 113, wherein the second drug is tolterodine, and the osmotic device provides a single dose plasma level for tolterodine in the range of about 0.5 to 25 ng per ml of plasma.

116) The osmotic device of claim 112 further comprising at least one external coat exterior to the membrane.

117) The osmotic device of claim 116, wherein the external coat is independently selected at each occurrence from water soluble and water erodible.

118) The osmotic device of claim 116, wherein the external coat is independently selected at each occurrence from inert and drug-containing.

119) The osmotic device of claim 116, wherein the external coat is independently selected at each occurrence from microporous, permeable, semipermeable and impermeable.

120) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 112, 113, 116-118 or 119.

121) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 114.

122) A method of treating incontinence in a subject comprising the step of administering an osmotic device according to claim 115.

123) A method of treating incontinence comprising the step of administering to a subject in need thereof oxybutynin and darifenacin.

124) The method of claim 123 wherein the oxybutynin and darifenacin are in the same dosage form.

125) The method of claim 124 wherein the oxybutynin and darifenacin are released from the dosage form in a controlled manner over an extended period of time.

126) The method of claim 123 wherein the oxybutynin and darifenacin are in separate dosage forms.

127) The method of claim 126 wherein the oxybutynin and darifenacin are released from their respective dosage forms in a controlled manner over an extended period of time.

128) A method of treating incontinence comprising the step of administering to a subject in need thereof oxybutynin and tolterodine.

129) The method of claim 128 wherein the oxybutynin and tolterodine are in the same dosage form.

130) The method of claim 129 wherein the oxybutynin and tolterodine are released from the dosage form in a controlled manner over an extended period of time.

131) The method of claim 128 wherein the oxybutynin and tolterodine are in separate dosage forms.

132) The method of claim 131 wherein the oxybutynin and tolterodine are released from their respective dosage forms in a controlled manner over an extended period of time.